

Pilot Program Request for Applications

The Penn Roybal Center on Palliative Care in Dementia, funded by the National Institute on Aging (NIA), aims to develop and test behavioral interventions, including those that leverage behavioral economic insights and data science methods, to improve palliative care delivery for persons with dementia (PWD) in long-term services and support (LTSS) facilities (e.g., nursing homes, assisted living facilities).

The goals of this pilot program are to: 1) support research that translates mechanistic insights from behavioral economics and data science into scalable interventions that change clinicians' and family caregivers' behaviors related to PWD in LTSS facilities; 2) facilitate collaborations and mentoring relationships among investigators from across the U.S. with expertise in all stages of behavioral intervention research and in key methodologic areas; and 3) launch and complete NIH Stage O-IV studies in real-world settings where Americans receive care.

We have partnered with Genesis HealthCare, one of the nation's largest LTSS companies, which will act as the learning lab for successfully funded pilots. Given the impact of the pandemic on LTSS facility clinicians and staff, it is possible that proposals that require appreciable hands-on effort on the parts of these essential workers will not be feasible. Thus, investigators are encouraged to propose projects that are as "hands-off" as possible from the perspective of LTSS facility clinicians and staff. If staff or clinician effort is required, investigators should specifically justify in their applications why it may be feasible.

Please note the following about our priorities:

- 1. We welcome applications related to the broad themes of palliative care delivery and advance care planning for persons with dementia in LTSS facilities and their family caregivers
- We specifically encourage applications that use methods from the fields of behavioral economics, data science, or both, but the most meritorious applications regardless of methodologic discipline(s) will be funded
- 3. We will only fund applications that include a clinical trial as <u>defined by the NIH</u> (which may be a pilot trial designed to test intervention acceptability, preliminary efficacy, or other early-phase outcomes). Proposals for multi-year awards may include research in the first year using other methods that will provide essential data in direct support of a clinical trial (e.g., testing of feasibility, acceptability, methods of identifying patients, etc), if the proposal includes a clinical trial in later years.

Areas of interest may include but are not limited to:

- Studies testing the impact of crisis management policies (visitation restrictions, staffing realignment) on patients, family caregivers, and clinicians
- Developing and testing risk-prediction algorithms for PWD (e.g., hospitalization risks), including studies that evaluate their effects in RCTs or propose to optimize their use for enrichment in future RCTs
- Trials testing nudges to modify patient, caregiver, or clinician behavior regarding any aspect of advance care planning, palliative care engagement, or other aspects of supportive care

We are also interested in supporting investigators from disciplines outside of dementia who may be shifting their career focus, such as through studies that:

- Test interventions targeting multi-morbid patients with dementia (e.g., those with dementia *AND* heart failure, COPD, chronic kidney disease, or other chronic serious illnesses)
- Compare interventions' effects among patients with dementia versus one or more other serious illnesses, if such comparisons will reveal unique barriers to high-quality palliative care in dementia or identify ways to surmount such barriers specifically for patients with dementia

Budget and duration: We will distribute up to \$200,000 in direct costs for pilot funding this year. Individual applicants may request budgets from \$25,000 to \$150,000 in direct costs per year, and may propose projects lasting 1 to 3 years (though 3 years will only be considered for large-scale and highly impactful studies). Additionally, proposals for Stage IV larger-scale trials may be eligible for cofunding from the NIA IMPACT Collaboratory, in which case larger budgets may be requested. Investigators interested in pursuing this option should send a 2-paragraph outline of the proposal and approximate trial duration and budget to Dr. Scott Halpern (shalpern@upenn.edu) no later than January 15, 2021.

We expect to fund 1-3 new pilot projects this cycle. Final funding decisions will be contingent on receipt of a sufficient number of meritorious applications. Awardees will be notified of funding decisions by **late February, 2021**. Successful applicants will then be responsible for completing all NIA-required Human Subjects Research forms and Data and Safety Monitoring plans within 4 weeks. Funding will begin **October 1, 2021** following NIA approval.

Partnership with Genesis HealthCare

Genesis HealthCare (Genesis) provides short to long-term healthcare services offering a wide variety of living options and professional clinical services in nearly 400 facilities across the nation. Their partnership with the Penn Roybal Center in Palliative Care in Dementia speaks to their dedication to innovation and discovery. Studies carried out in Genesis facilities will have the benefit of support from a multi-disciplinary team from Penn and Genesis. The impact of the COVID-19 pandemic on LTSS facilities cannot be overstated – as policies and priorities evolve at Genesis we will work with awardees to make adjustments to research plans as needed. You can learn more about Genesis and its facilities and resources here. Specific questions about Genesis can be emailed to pair@pennmedicine.upenn.edu.

We will also consider proposals from investigators who would like to conduct their studies in facilities outside of Genesis with whom they have preexisting relationships. These investigators should describe the nature of their collaboration in the research plan, and provide letter(s) of support from company or facility leadership. Such letters would not count toward the page limit.

Eligibility and Criteria

Penn Roybal Center on Palliative Care in Dementia-affiliated faculty members and their trainees (junior faculty and/or post-doctoral fellows) are eligible to apply for funding. There are presently 44 affiliated investigators at Penn, plus affiliated investigators at the following institutions:

Brown School of Public Health
Weil Cornell Medical College
Drexel College of Nursing and Health Professions
Florida Atlantic University
Harvard School of Medicine
Icahn School of Medicine at Mount Sinai

Indiana University School of Medicine Oregon Health Science University Penn State College of Nursing University of North Carolina School of Medicine Yale School of Medicine

If you are a postdoctoral fellow or faculty member at one of the 11 institutions listed above, or a faculty member at the Assistant Professor rank or above at another academic research institution, and you would like to become an affiliated investigator please email your NIH biosketch and a brief explanation of your request to pair@pennmedicine.upenn.edu. Benefits of affiliation include eligibility for pilot funds and to attend Penn Roybal Center on Palliative Care in Dementia events, such as our annual symposium.

Pilots are encouraged to use the <u>NIH Stage Model of behavioral intervention development</u>. All pilot applicants must describe the relevant Stage(s) for the proposed work. The definition of each stage can be found using the link above.

Submissions will be evaluated on the following criteria:

- Fit with the Roybal Center's themes of behavioral economics and data science
- Fit with NIH Stage Model
- Inclusion of a clinical trial
- Potential to lead to future funding of effectiveness and/or implementation trials
- Inclusion of investigators from multiple disciplines
- Importance of knowledge to be gained
- Scientific rigor

Other Requirements

A one-page annual progress report must be submitted in March 2022 that includes a description of the project's specific aims, significance, summary of the research conducted and results found to date, total enrollment, and future plans. A member of the research team must present study findings at the annual Penn Roybal Center on Palliative Care in Dementia Research Symposium. The symposium is tentatively planned for in March 2022. We have yet to determine if the Symposium will be in-person or virtual. In the event of an in-person meeting, travel expenses will be covered by the Penn Roybal Center.

To receive funding you will need to have obtained IRB approval, if applicable, and posted the project on ClinicalTrials.gov, if applicable, prior to enrolling participants. The proposed project and budget will need to be approved by the National Institute on Aging. You must list the Penn Roybal Center on Palliative Care in Dementia in any publications resulting from this work. Any publications that are the result of

this funding must mention: "The project described was supported in part by Grant Number P30AG064105-01 from the National Institute on Aging."

Additional Budget Guidance

Guidance for University of Pennsylvania Investigators

Please use the federal fringe rates (FY22). The funding mechanism supporting this RFA is funded by the National Institute on Aging (P30 AG064105). Please use guidance set forth by NIH here regarding unallowable expenditures when building your budget. A detailed budget and budget justification is required as part of the submission.

Guidance for investigators at other institutions

The funding mechanism supporting this RFA is funded by the National Institute on Aging (P30 AG064105). Please use guidance set forth by NIH here regarding unallowable expenditures when building your budget. A detailed budget, budget justification and a copy of your institution's DHHS Rate Agreement is required as part of the submission. A maximum overhead rate of 46.5% will be provided.

How to Apply

Please submit an electronic (.pdf) application via email pennmedicine.upenn.edu by February 1, 2021, at 5 pm EDT. See below for application content and documents.

The application must include the following:

- Face Page:
 - o <u>Template for Penn Investigators</u>
 - Template for non-Penn Investigators
- **Abstract Page:** The abstract text should be no longer than 250 words.
- **Budget**: Please use the <u>PHS 398 template</u> budget page and provide detailed expenses. Salary support for faculty is discouraged.
- **Budget Justification:** Please provide a short justification for all personnel, supplies, and equipment that will be expensed to this project.
- NIH Biosketch: An NIH format biosketch must be submitted for the PI and Co-Is.
- Research Strategy: The research proposal should be no longer than three single-spaced pages
 with one-inch margins and should include the essential background information relative to the
 project, as well as justification of feasibility during or shortly following the COVID-19 pandemic.
 If the feasibility justification is complex, we will allow an additional half-page to flesh out this
 section. Please use Arial size 11 font. References should be attached to your research proposal
 and will not count toward your three-page limit. Please provide a timeline of implementation to
 ensure meeting all milestones by the end of the funding period.
- Letters of Support: Letters of support are always acceptable, but are only required if investigators propose studies conducted outside of Genesis Healthcare facilities, in which case letter(s) from LTSS company or facility leadership will be important.

For scientific inquiries, please reach out to Dr. Scott Halpern (shalpern@upenn.edu) or Dr. Jason Karlawish (Jason.karlawish@pennmedicine.upenn.edu). For administrative questions about the proposal process please reach out to Beth Cooney-Zingman (elcooney@upenn.edu)